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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,339	01/26/2004	Shawn R. Feaster	034047.003.1 (00-23)	7108
53502	7590	07/25/2006	EXAMINER	
OFFICE OF THE STAFF JUDGE ADVOCATE (SKS) U.S. ARMY MED. RESEARCH & MATERIAL COMMAND 504 SCOTT STREET ATTN: MCMR-JA (MS. ELIZABETH ARWINE) FORT DETRICK, MD 21702-5012			SHEN, BIN	
			ART UNIT	PAPER NUMBER
			1655	
DATE MAILED: 07/25/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/763,339

Applicant(s)

FEASTER ET AL.

Examiner

Bin Shen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 29-36, 38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) 31-34, 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29, 30, 35, 38 and 39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election***

Applicant's election with traverse of Group I, claims 29, 30, 35, 38 and 39, in the reply filed on 5/31/2006 is acknowledged. The traversal is on the ground(s) that the search for Groups II and III would not be an undue burden. This is not found persuasive because Group III has acquired a separate status in the art as shown by its different classification, and the kit of Group II has a different detection mode, thus there is undue burden to search the groups together.

The requirement is still deemed proper and is therefore made FINAL.

The IDS received 1/24/2004, the preliminary amendment received 1/24/2004 have been entered.

Claims 31-34, and 36 are nonelected and thus are withdrawn from further consideration. Only claims 29, 30, 35, 38 and 39 are presented for examination on the merits.

### ***Specification***

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

2. The uses of the trademarks "Test-Mate OP" and "I-STAT" on pages 28, 47-49, "Vacutainers" on pages 29 and 30 have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be

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respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38 contains the trademark/trade names "i-STAT, Test-Mate OP, Biomek 2000". Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademarks/trade names are used to identify/describe the devices and, accordingly, the identification/description is indefinite. Applicant must remove the trademark from the claim and claim the device in generic terms.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 29 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Dorette et al. (Applied Biochemistry and Biotechnology 1998;74:1-12).

Dorette et al. teach an enzyme biosensor (read as a device) for the determination of cholinesterase on polymer membrane (see abstract). The biosensor uses physical entrapment strategies (same function as a sealed chamber, see page 2, line 11-14) to co-immobilize acetylcholinesterase/choline oxidase (AChE/ChO) or butyrylcholinesterase/ChO (BChE/ChO), and it detects activities/concentrations of different substrates (read on as a plurality of proteins, see page 2, 7<sup>th</sup> paragraph). The sensitivity for each substrate and for each protein is determined by measuring the reaction rates at different concentrations through calculating a linear relationships (see Fig. 1, Fig. 3 and Table 1).

Therefore, the cited reference is deemed to anticipate the instant claims above.

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 29, 30, 35, 38, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doretti et al. in view of Magnotti et al. (Clinica Chimica Acta, 1988;315:315-332), and further in view of Ellman et al. (Biochemical Pharmacology 1961;7:88-95).

Doretti et al. teach what is above.

Doretti et al. do not teach use of a handheld device with a cartridge to detect cholinesterase.

Magnotti et al. teach the reagents (see pages 317-318) needed for the testing device and the advantages to develop a portable and convenient device/kit (read on as handheld) with stable, premixed reagents (read on as cartridge) to measure cholinesterases in a field assay (see abstract and also page 329, 3<sup>rd</sup> full paragraph) because field monitoring erythrocyte and plasma cholinesterase activities is beneficial to agricultural workers and others at risk for pesticide exposure (see page 331, 2<sup>nd</sup> full paragraph).

Ellman et al. teach a new and rapid colorimetric determination of acetylcholinesterase activity which is later developed into the Test-Mate OP kit by EQM Research Inc., Cincinnati, OH, USA (as stated on page 1078, lines 11-14 of Paz-

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y-Mino et al. Environmental Health Perspectives 2002;110:(1077-1080)).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to develop a handheld device with a biosensor (as taught by Dorette et al.) and a cartridge (whose convenience is suggested by Magnotti et al.) to monitor enzyme activity because Dorette et al. teach a biosensor to detect enzyme activity, and Magnotti et al. teach the reagents that are needed for the enzyme assay and suggest to develop a portable and convenient device to monitor cholinesterases activity in the field. One would have been motivated to make the modification because Magnotti define the optimal criteria for field measurement of cholinesterase (see page 328, 1<sup>st</sup> paragraph of Discussion) and the need for a portable/handheld device/kit with stable, premixed reagents (cartridge), and would reasonably have expected success because Dorette et al. teach how to make a biosensor for cholinesterase detection, and Magnotti et al. teach many advantages of developing a portable, convenient and stable assay system to be used in the field.

The Test-Mate OP system has all the components that are required for the detection of cholinesterase as described by Ellman et al., thus it would have been obvious to one of ordinary skill in the art to use the Test-Mate OP kit to detect, measure or monitor the activities or concentrations of cholinesterase instead of the claimed device.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to

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one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### **Conclusion**

6. No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Paz-y-Mino et al. teach the monitoring of cholinesterase with the Test-Mate OP kit.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent



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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey can be reached at (571) 272-0775.



MICHAEL MELLER  
PRIMARY EXAMINER

*B Shen*

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